

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MASSACHUSETTS
3 DOCKET NO. 1:13-MD-2419 (RWZ)
4 IN RE: NEW ENGLAND COMPOUNDING
5 PHARMACY, INC. PRODUCTS
6 LIABILITY LITIGATION

7 THIS DOCUMENT RELATES TO:

8 ARMETTA, ET AL. V. BOX HILL SURGERY CENTER,
9 LLC, ET AL.
10 NO. 1:14-CV-14022-RWZ

11 BOWMAN, ET AL. V. BOX HILL SURGERY CENTER,
12 LLC, ET AL.
13 NO. 1:14-CV-14028-RWZ

14 DAVIS, ET AL. V. BOX HILL SURGERY CENTER,
15 LLC, ET AL.
16 NO. 1:14-CV-14033-RWZ

17 DREISCH, ET AL. V. BOX HILL SURGERY CENTER,
18 LLC, ET AL.
19 NO. 1:14-CV-14029-RWZ

20 FARTHING, ET AL. V. BOX HILL SURGERY CENTER,
21 LLC, ET AL.
22 NO. 1:14-CV-14036-RWZ

23 KASHI, ET AL. V. BOX HILL SURGERY CENTER,
24 LLC, ET AL.
25 NO. 1:14-CV-14026-RWZ

TORBECK, ET AL. BOX HILL SURGERY CENTER,
LLC, ET AL.
NO. 1:14-CV-14023-RWZ

HANDY, ET AL. V. BOX HILL SURGERY CENTER,
LLC, ET AL.
NO. 1:14-CV-14019-RWZ

DEPONENT: LAXMAIAH MANCHIKANTI, M.D.

DATE: FEBRUARY 16, 2017

REPORTER: CHELSEA SEVILLA-LOZADA

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<p>1 APPEARANCES</p> <p>2</p> <p>3 ON BEHALF OF THE PLAINTIFFS:</p> <p>4 JAY D. MILLER</p> <p>5 SILVIO TRENTALANGE</p> <p>6 LAW OFFICES OF PETER G. ANGELOS, P.C.</p> <p>7 100 NORTH CHARLES STREET, 22ND FLOOR</p> <p>8 BALTIMORE, MARYLAND 21201</p> <p>9 TELEPHONE NO.: (410) 649-2000</p> <p>10 E-MAIL: JMILLER@LAWPGA.COM</p> <p>11</p> <p>12 AND</p> <p>13</p> <p>14 HARRY M. ROTH</p> <p>15 COHEN PLACITELLA & ROTH, P.C.</p> <p>16 201 MARKET STREET, SUITE 2900</p> <p>17 PHILADELPHIA, PENNSYLVANIA 19103</p> <p>18 TELEPHONE NO.: (215) 567-3500</p> <p>19 E-MAIL: HROTH@CPRLAW.COM</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 INDEX</p> <p>2 Page</p> <p>3 DIRECT EXAMINATION BY MR. MILLER 6</p> <p>4 EXAMINATION BY MR. ROTH 113</p> <p>5 CROSS EXAMINATION BY MR. KIRBY 177</p> <p>6 REEXAMINATION BY MR. ROTH 192</p> <p>7</p> <p>8</p> <p>9 EXHIBITS</p> <p>10 Page</p> <p>11 34 FDA BRIEFING 62</p> <p>12 36 ASSESSMENT OF INFECTION CONTROL 123</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
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<p>1 APPEARANCES (CONTINUED)</p> <p>2</p> <p>3 ON BEHALF OF THE DEFENDANT, BOX HILL SURGERY CENTER:</p> <p>4 GREGORY K. KIRBY</p> <p>5 PESSIN KATZ LAW, P.A.</p> <p>6 901 DULANEY VALLEY ROAD, SUITE 500</p> <p>7 TOWSON, MARYLAND 21204</p> <p>8 TELEPHONE NO.: (410) 938-8800</p> <p>9 E-MAIL: GKIRBY@PKLAW.COM</p> <p>10</p> <p>11 ON BEHALF OF THE DEFENDANT, SPECIALTY SURGERY CENTER:</p> <p>12 ASHLEY GENO</p> <p>13 BREWE, KRAUSE, BROOKS & CHASTIN, PLLC</p> <p>14 611 COMMERCE STREET, SUITE 2600</p> <p>15 NASHVILLE, TENNESSEE 37203</p> <p>16 TELEPHONE NO.: (615) 256-8787</p> <p>17 E-MAIL: AGENO@BKBLAW.COM</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 STIPULATION</p> <p>2</p> <p>3 The deposition of LAXMAIAH MANCHIKANTI, M.D. taken at</p> <p>4 THE PAIN CENTER, 2831 LONE OAK ROAD, PADUCAH, KENTUCKY</p> <p>5 42003 on THURSDAY, the 16TH day of FEBRUARY, 2017 at</p> <p>6 approximately 10:00 A.M. CST; said deposition was taken</p> <p>7 pursuant to the FEDERAL Rules of Civil Procedure. It is</p> <p>8 agreed that CHELSEA SEVILLA-LOZADA, being a Notary</p> <p>9 Public and Court Reporter for the State of Kentucky, may</p> <p>10 swear the witness.</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

<p style="text-align: right;">Page 74</p> <p>1 Q And in that book, don't you indicate that it's</p> <p>2 very important to put down the specific drug that's</p> <p>3 being used by the doctor?</p> <p>4 A That's correct.</p> <p>5 Q So that if you're really not using Depo-</p> <p>6 Medrol, but rather a compounded drug, shouldn't Dr.</p> <p>7 Bhambhani have indicated that in her patient's charts,</p> <p>8 rather than writing Depo-Medrol?</p> <p>9 MR. KIRBY: Objection. Go ahead.</p> <p>10 A Well, she's -- I'm saying specific drug is</p> <p>11 that you are using lidocaine, you are using Depo-</p> <p>12 Medrol. Those are the issues. You use</p> <p>13 methylprednisolone. I'm not saying that you have to use</p> <p>14 a generic name or a pharmacological name, or a brand</p> <p>15 name, so that issue was not an issue at that time, and I</p> <p>16 have routinely dictated that if I use a Depo-Medrol,</p> <p>17 even though it was from NECC, or from another</p> <p>18 compounder, I called it Depo-Medrol, only the difference</p> <p>19 was that if I use a preservative free, I would say it is</p> <p>20 preservative free.</p> <p>21 Q You issued a 24-page report at your last --</p> <p>22 A A 24-page report on what?</p> <p>23 Q Your expert report in this case.</p> <p>24 A Oh, in this case. Yes, sir. I do. I have</p> <p>25 that right here.</p>	<p style="text-align: right;">Page 76</p> <p>1 A I'm not a very good typist. I'm extremely</p> <p>2 poor, my technical skills are not very good in typing.</p> <p>3 I'm a good physician, but not a typist. I have</p> <p>4 transcriptionists, they type if I dictate. Here, we</p> <p>5 prepared this document together with the discussions, so</p> <p>6 I believe his office may have typed it.</p> <p>7 Q Okay. So this 28 pages was typed at Mr.</p> <p>8 Kirby's office and sent to you, and then you signed it?</p> <p>9 MR. KIRBY: Objection to form. Again, it's</p> <p>10 protected information. Privileged information.</p> <p>11 A No. As I said, we -- I reviewed the</p> <p>12 documentation first, then we had a meeting. This was</p> <p>13 about two hours or so. We discussed all these issues.</p> <p>14 We went one by one, and he started writing down, I'm</p> <p>15 very bad at shorthand either, so after that, then it was</p> <p>16 typed and it came to me. I made corrections, and then</p> <p>17 the final document was produced.</p> <p>18 Q Have you reviewed the reports of any other</p> <p>19 pain management physicians in this case?</p> <p>20 A I have reviewed the report of Dr. Saberski,</p> <p>21 Saberski or Saberski, whatever.</p> <p>22 MR. KIRBY: Saberski.</p> <p>23 A Saberski, no, I can't say it. Saberski.</p> <p>24 Saberski.</p> <p>25 Q Box Hill, you read Dr. Main's (phonetic)</p>
<p style="text-align: right;">Page 75</p> <p>1 Q I've got 24 typed pages that they're first</p> <p>2 person. It is my opinion, it is my belief. It is</p> <p>3 written in the first person. Did you, or someone in</p> <p>4 your office, sit down and type out these 24 pages?</p> <p>5 MR. KIRBY: Objection to form. It's privileged</p> <p>6 protected information in Rule 26.</p> <p>7 MR. MILLER: You can answer.</p> <p>8 BY MR. MILLER:</p> <p>9 A Well, we had both of us, the attorney, Mr.</p> <p>10 Kirby and I, discussed these issues. I reviewed the</p> <p>11 documentation first, and then we discussed with this and</p> <p>12 jointly we came up with this report.</p> <p>13 Q Oh, who typed it?</p> <p>14 MR. KIRBY: Objection to form. Drafting is not</p> <p>15 discoverable.</p> <p>16 Q I didn't ask you who drafted it. I said who</p> <p>17 typed it.</p> <p>18 MR. KIRBY: Yeah. Same objection. If you</p> <p>19 recall.</p> <p>20 MR. MILLER: Why don't you suggest to him that</p> <p>21 he not recall.</p> <p>22 BY MR. MILLER:</p> <p>23 Q In court, every question is if you can recall,</p> <p>24 Doctor, if you can remember. Do you remember typing a</p> <p>25 24-page report?</p>	<p style="text-align: right;">Page 77</p> <p>1 report?</p> <p>2 A No. Dr. Main, who is that? Is that in there?</p> <p>3 I don't recall.</p> <p>4 Q He was an expert also hired by Box Hill.</p> <p>5 A No. I have not reviewed any of their expert's</p> <p>6 reports. I have only reviewed your expert's reports to</p> <p>7 the best of my knowledge.</p> <p>8 Q But you are -- are you confident that all of</p> <p>9 the information in here that says that it's my opinion,</p> <p>10 that they are truly your opinions?</p> <p>11 A Yes, sir. I am.</p> <p>12 Q If you could go to page 4?</p> <p>13 A Yes.</p> <p>14 Q Section B, medication purchasing by the Box</p> <p>15 Hill defendants.</p> <p>16 A Yes.</p> <p>17 Q Apparently, Dr. Main has a very -- medication</p> <p>18 purchased by the Box Hill defendant, as well.</p> <p>19 A I didn't understand your prior comment. I'm</p> <p>20 looking at page 4, Section B, medication purchasing by</p> <p>21 the Box Hill defendants, and you made some other comment</p> <p>22 after that. I didn't hear that.</p> <p>23 Q I said did Dr. Main, another expert in this</p> <p>24 case, as a Section B with the same exact title, matter</p> <p>25 of fact, almost the entire report is the same as yours,</p>

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<p>1 but we'll get to that.</p> <p>2 MR. KIRBY: Move to strike. No question. Go</p> <p>3 ahead.</p> <p>4 A Oh, well --</p> <p>5 MR. KIRBY: There's no question. Just wait.</p> <p>6 A Next question.</p> <p>7 Q Go down to the second paragraph that begins</p> <p>8 "Box Hill ordered." Do you see that?</p> <p>9 A Yes.</p> <p>10 Q This is a prescription order form provided by</p> <p>11 NECC. Have you actually reviewed the actual</p> <p>12 prescription order forms that Dr. Bhambhani used in this</p> <p>13 case?</p> <p>14 A Yes. I have.</p> <p>15 Q And are you aware that she was sending names</p> <p>16 that were simply on a schedule that she had seen. Did</p> <p>17 you see that?</p> <p>18 MR. KIRBY: Objection to form. You can answer.</p> <p>19 A Yeah. I saw that she sent the schedules. I</p> <p>20 don't understand what the question is. I saw that she</p> <p>21 was sending the schedules, and some of them had the</p> <p>22 names, but sometimes she just sent the see attached, the</p> <p>23 schedule.</p> <p>24 Q Right. But the schedule she is sending is a</p> <p>25 schedule of patients that she has already treated, so</p>	<p>1 you talking about? States, federal, I don't know,</p> <p>2 what are you talking about?</p> <p>3 BY MR. MILLER:</p> <p>4 Q Well, I can give you a list of them. Are you</p> <p>5 familiar with the Maryland Law co-wire (phonetic) that</p> <p>6 requires single prescriptions for individual patients?</p> <p>7 A Yes. I have seen that, but that is meant for</p> <p>8 the pharmacist and it is -- it did not come from</p> <p>9 Maryland Board of Medical Licensure. Also, it is for</p> <p>10 controlled substances. You just stated controlled</p> <p>11 substances. So this is not a controlled substance.</p> <p>12 Q Well, under Massachusetts definition, all</p> <p>13 drugs are controlled substances, are they not?</p> <p>14 MR. KIRBY: Objection.</p> <p>15 A I'm not aware of that.</p> <p>16 Q Are you aware of the Massachusetts statute</p> <p>17 that requires single prescription -- individual</p> <p>18 prescription for individual patients?</p> <p>19 MR. KIRBY: Objection to form.</p> <p>20 A Again, I have seen that several places in this</p> <p>21 documentation when I was going through, but these are</p> <p>22 all pharmacy directions. None of them is related from</p> <p>23 the Board of Medical Licensure. It is not controlling</p> <p>24 the practice of medicine. If that is the case, many of</p> <p>25 the doctors are not using that regulation as you call</p>
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<p>1 you would treat 12 patients on October 12th, October the</p> <p>2 13th, she filled out a prescription order form and</p> <p>3 attaches that sheet, which is merely a list of names of</p> <p>4 patients she saw the previous day.</p> <p>5 MR. KIRBY: Objection to form. Is there a</p> <p>6 question?</p> <p>7 MR. MILLER: I'm getting to it.</p> <p>8 MR. KIRBY: Okay.</p> <p>9 BY MR. MILLER:</p> <p>10 Q Is it your opinion that that's appropriate?</p> <p>11 A Well, if she is going to use the -- if she's</p> <p>12 going to inject the steroids in the same patients again,</p> <p>13 Yes. It is appropriate.</p> <p>14 Q Okay. If she's not, then it would not be</p> <p>15 appropriate, correct?</p> <p>16 MR. KIRBY: Objection to form.</p> <p>17 A At least she was under the belief that they</p> <p>18 were coming back for the injections, that's why they</p> <p>19 were on the list, and that is the reason she provided</p> <p>20 the list. That is my interpretation of what I</p> <p>21 understood from her deposition, as well as looking at</p> <p>22 the forms.</p> <p>23 Q Are you familiar with the regulation that</p> <p>24 requires single prescriptions for individual patients?</p> <p>25 MR. KIRBY: Objection. Where is it -- what are</p>	<p>1 it. I'm not sure if it is a regulation, or guideline,</p> <p>2 or policy. In any case, we have done the same thing and</p> <p>3 the majority of physicians I know of who have ordered</p> <p>4 from NECC, uses the same format. In the beginning, we</p> <p>5 didn't even give patient's names, and later on, they</p> <p>6 asked us to give us the names of the patients we will be</p> <p>7 using, so we will just routinely send the schedules and</p> <p>8 or we send the names of the patients. We -- of course,</p> <p>9 we send only the patients where they will be receiving</p> <p>10 the epidural injections, or that will be receiving the</p> <p>11 steroids.</p> <p>12 Q Can you go to page -- I mean Exhibit number</p> <p>13 13? It's a few pages in, Exhibit 13. It's a</p> <p>14 prescription order form.</p> <p>15 MR. KIRBY: We're working on it. Hold on one</p> <p>16 second. He has it in front of him if you -- just so</p> <p>17 you know.</p> <p>18 BY MR. MILLER:</p> <p>19 Q Okay. So in the first column where it says</p> <p>20 "Name of patient," and it says "see attachment of</p> <p>21 patient names." Do you see that?</p> <p>22 A Yes.</p> <p>23 Q The next one says "One patient five vials." Do</p> <p>24 you see that?</p> <p>25 A Yes.</p>

<p style="text-align: right;">Page 162</p> <p>1 way to anybody or any agency?</p> <p>2 A No, sir. No, I have not.</p> <p>3 Q I want to ask you to turn to page 11 of your</p> <p>4 report.</p> <p>5 MR. KIRBY: Page 11.</p> <p>6 A Yes, sir. I'm there.</p> <p>7 Q And under sub-part 3, the last sentence reads,</p> <p>8 "All of these factors support the conclusion that it was</p> <p>9 reasonable and appropriate for STOPNC to purchase</p> <p>10 compounded MPA, which is a reasonable equivalent to</p> <p>11 Depo- Medrol." What is STOPNC?</p> <p>12 A I think it is the facility name in Tennessee.</p> <p>13 I think it is St. Thomas Outpatient Neuro-surgery</p> <p>14 Center, if I'm not wrong.</p> <p>15 Q And what does STOPNC have to do with anything,</p> <p>16 with Dr. Bhambhani's practice or Box Hill Pain Center?</p> <p>17 A Oh, they were the first ones involved in this</p> <p>18 issue, and they had many of the documents. Their names</p> <p>19 were mentioned everywhere in the documents I was</p> <p>20 reading. I think I even reviewed some of the depositions</p> <p>21 taken by them.</p> <p>22 Q Are you expressing any opinion about SSTOPNC</p> <p>23 in these cases?</p> <p>24 MR. KIRBY: I think he said he just had STOPNC</p> <p>25 on the brain after reviewing those cases, that other</p>	<p style="text-align: right;">Page 164</p> <p>1 or actually preservative-free MPA because of a concern</p> <p>2 for potential adverse events. My first question is do</p> <p>3 you know -- does -- are there any preservatives --</p> <p>4 excuse me -- were there any preservatives in NECC's</p> <p>5 compounded steroid?</p> <p>6 A Yes, I think they have polyethylene glycol. I</p> <p>7 don't know what else they have. They just don't have</p> <p>8 the alcohol in it.</p> <p>9 Q Okay. And does polyethylene glycol cause or</p> <p>10 pose any risks to patients?</p> <p>11 A If you exceed 30 percent of the volume, the 30</p> <p>12 percent does. So it can suppress the nerve conductions,</p> <p>13 but it has not been shown to cause any permanent damage</p> <p>14 or neural tissue damage.</p> <p>15 Q Okay. And so then, the presence of</p> <p>16 polyethylene glycol as a preservative means that it's</p> <p>17 not really preservative-free; is that right?</p> <p>18 MR. KIRBY: Objection to form. Foundation. You</p> <p>19 can answer.</p> <p>20 A Yeah, that's correct. As you asked the</p> <p>21 question, I'm just realizing that it is a misnomer to</p> <p>22 call it "preservative-free." I never thought about</p> <p>23 that.</p> <p>24 Q And there is data that suggests that</p> <p>25 polyethylene glycol as preservative can be neurotoxic?</p>
<p style="text-align: right;">Page 163</p> <p>1 stuff, but if you know different?</p> <p>2 A Well, I have --</p> <p>3 BY MR. ROTH:</p> <p>4 Q But --</p> <p>5 A -- reviewed those, and then that it just says</p> <p>6 that they also protested them, and the factors -- the</p> <p>7 people who gave the depositions said that it was</p> <p>8 reasonable and appropriate for them to purchase</p> <p>9 compounded MPA.</p> <p>10 Q Okay. But Dr. Bhambhani never relied on</p> <p>11 anybody from STOPNC in making a decision to purchase</p> <p>12 from NECC, did she?</p> <p>13 A No, she did not. She relied on her own</p> <p>14 experience, and also her former colleagues, their</p> <p>15 experience, one or two people's experience. She was not</p> <p>16 involved in this. We were just -- we were just making a</p> <p>17 case about using alternate to Depo-Medrol -- alternate</p> <p>18 to Depo-Medrol.</p> <p>19 MR. KIRBY: Harry, I think it's just a typo,</p> <p>20 but I mean, you can ask whatever questions you want,</p> <p>21 but this is just a typo.</p> <p>22 BY MR. ROTH:</p> <p>23 Q Let me -- let me shift gears for you a little</p> <p>24 bit -- with you a little bit, Doctor. One of the things</p> <p>25 you've talked about is that Dr. Bhambhani's used any --</p>	<p style="text-align: right;">Page 165</p> <p>1 A Well, it can suppress the nerve conduction at</p> <p>2 30 percent level or 40 percent level, one of the higher</p> <p>3 concentrations. In Depo-Medrol, it was only 33 percent</p> <p>4 when we -- when you buy from Pfizer or Upjohn, I don't</p> <p>5 know exact concentration at NECC.</p> <p>6 Q Okay. That would be important to know in</p> <p>7 terms of a physician's interest in buying something that</p> <p>8 is preservative-free; wouldn't it?</p> <p>9 MR. KIRBY: Objection.</p> <p>10 Q How much preservative is actually in the drug?</p> <p>11 A She was focusing mostly on alcohol, plus the</p> <p>12 side-effects she experienced with the other drugs. So</p> <p>13 polyethylene glycol generally was not considered as a</p> <p>14 neurotoxic. I understand there is some level to which</p> <p>15 it does suppress neuro fibers, but there is no</p> <p>16 significant literature to state that. There is more</p> <p>17 literature in reference to alcohol, and many people did</p> <p>18 not blame polyethylene glycol for any arachnoiditis</p> <p>19 cases.</p> <p>20 Q The reason I'm asking that, and I'm again, I'm</p> <p>21 trying to frame it in a fair way, there is because in</p> <p>22 your text, which cites other literature, you have</p> <p>23 written that there is not really, I'm sorry, more</p> <p>24 specifically, what you have written is that "Other</p> <p>25 authors have concluded that despite what has been</p>